Remarks

Telephone Interview

Applicants thank Examiner Monshipouri for the telephone interview with their representative, Dr. Anne Carlson, on November 6, 2008, during which the requirement for an election of species (Office action at page 2) was addressed. Examiner Monshipouri confirmed that the paragraph discussing species election was a generic form paragraph and that the species election should be ignored if the claims do not include species. Applicants believe that no species election is required. Thus, the election of a Group, as discussed below, fulfills the requirement for responding the Restriction Requirement.

Response to Restriction

Claims 1-14 of this §371 National Stage application are pending and are indicated as being subject to a restriction requirement. In particular, the following Groups have been designated:

Group I.	Claims 1-3 and 9, drawn to DM43 protein composition and a method of use thereof for inhibiting metalloproteinases in human cells;
Group II.	Claims 4-5 and 10-11, drawn to a method of treatment of tumor diseases in human comprising administering said DM43 protein consumption;
Group III.	Claims 6-7 and 12-13, drawn to a method of treatment of central nervous system utilizing said DM43 protein composition; and
Group IV.	Claims 8 and 14, drawn to a method of treatment of osteoarthritis diseases using said composition.

The Office action states that Groups I-IV "are not so linked as to form a single general inventive concept under PCT Rule 13.1" and that the Applicant is required "to elect a single invention to which the claims must be restricted" (Office action at page 2). Applicants respectfully disagree and submit that the claims of Groups I-IV do in fact relate to a single special technical feature, which feature makes a contribution over the prior art. As such, all of the claims should be examined together. Applicant requests that the requirement be withdrawn in light of the arguments herein.

Standard for Analyzing Unity of Invention

37 CFR § 1.475 requires unity of invention in a national stage application such as this; unity of invention is present when a group of inventions are "so linked as to form a single general inventive concept." [*See* 37 CFR § 1.475(a).] "A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature." [MPEP § 1893.03(d). *See also* 37 CFR § 1.475(a).]

Further, "The expression 'special technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." [*See* 37 CFR § 1.475(a), emphasis added.]

This makes it clear that an analysis with regard to unity of invention occurs in two stages. First, is there a special technical feature shared among the claims/groups of inventions, such that they are linked to form a single inventive concept? If there is, then one asks does that special technical feature **define a contribution over the prior art** for each of the claimed inventions? If no relevant prior art is identified, then there can be no finding of lack of unity.

Applying the Standard in the Current Case

The invention as claimed relates to a therapeutically active DM43. The Written Opinion of the International Searching Authority (dated August 8, 2005; **Exhibit A**, attached) for the corresponding PCT application determined that this subject matter was both novel and inventive (Exhibit A, page 3). Thus, the special technical feature shared among all of the claims is the **therapeutically effective amount of DM43**. Moreover, as claims 4-8 and 10-14 (Groups II-IV) all depend, directly or indirectly, from claim 1 (thereby incorporating all of the limitations thereof), the claims of Groups II-IV all relate to the special technical feature of a therapeutically effective amount of DM43 of Group I. Furthermore, the Written Opinion indicates that there is no lack of unity of invention among the claims (Exhibit A, page 1). In view of the above discussion, Applicants respectfully submit that Groups I through IV are linked to form a single general inventive concept.

As the Written Opinion states that a therapeutically effective amount of DM43 is novel and inventive, and as Office has provided neither allegation nor evidence that this subject matter is disclosed or rendered obvious by the prior art, this feature clearly constitutes an appropriate "corresponding special technical feature" sufficient for the fulfillment of the unity of invention requirement. [*See* 37 CFR § 1.475(a); MPEP § 1893.03(d).]

In summary, as required by 37 CFR §1.475, the claims pending in the application have unity of invention because they are directed "to a group of inventions so linked as to form a single general inventive concept" because "there is a technical relationship among [the] inventions involving one . . . corresponding technical feature[]" – a therapeutically effective amount of DM43 – and this special technical feature "define[s] a contribution . . . over the prior art."

As unity of invention exists among all of the Groups in the present application, Applicants submit that it is inappropriate to subject the claims to a requirement for restriction. In addition, Applicants note that the MPEP states that "[i]f the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention" (see "Unity of Invention", Section (c)(i), Annex B to the Administrative Instructions under the PCT, MPEP). Claims 4-8 and 10-14 (Groups II-IV) depend, directly or indirectly, from claim 1. Thus, if claim 1 is allowed, Applicants respectfully request that all of the claims be examined in the current case.

Election

Under protest, and only to comply with 37 CFR §1.499, Applicants hereby provisionally elect Examiner's Group I (claims 1-3 and 9), drawn to DM43 protein composition and a method of use thereof for inhibiting metalloproteinases in human cells. In accordance with the current Patent and Trademark Office Guidelines for Restriction Requirements in TC1600, Applicants respectfully request that method claims which depend from or otherwise include all the limitations of any allowed composition claims be rejoined and examined.

Conclusion

It is believed that the application is in condition for substantive examination. If any minor matters remain to be addressed prior to examination, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

One World Trade Center, Suite 1600
121 S.W. Salmon Street
Portland, Oregon 97204
Telephone: (503) 595-5300
Facsimile: (503) 595-5301

By /Anne Carlson/
Anne Carlson, Ph.D.
Registration No. 47,472